



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 19 2002

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Secondary Review of Information/Data Submitted to Support Registration of a New Product "RootGro" Containing Indole-3-butyric Acid (IBA) as the Active Ingredient (DP 278792; Case 071111; Submission S604740)

TO: Todd Peterson, RAL
Biochemical Pesticides Branch (BPB)
Biopesticides and Pollution Prevention Division (BPPD)

FROM: Roy Sjoblad
BPB, BPPD

This Memorandum Contains Confidential Business Information

Background: LT BioSyn Inc. requests the registration of RootGro to promote root growth of cuttings from plants, shrubs and trees. In general, cuttings are dipped in the product for 3-5 seconds before placing in planting medium.

Conclusions: The only deficiency in the submission is the incorrect CAS number for the active ingredient on the CSF.

Review of Data/Information Submitted:

MRID 454769-01: Product Identity (830.1550); Description of Beginning Materials (830.1600); Description of Formulating Process (830.1650); Formation of Impurities (830.1670); Certified Limits (830.1750); Enforcement Analytical Method (830.1800).

The study is **Acceptable**. The following issues were raised during the primary review. It was not clear whether the nominal concentration of the active ingredient on the CSF was adjusted for purity of the source material (98% IBA). The CAS number for IBA on the CSF was incorrect. (the correct CAS No. being 133-32-4). The certified limits are acceptable, no impurities are produced during formulation, and the enforcement analytical method is HPLC.

MRID 45476-02: Physical and Chemical Characteristics (830.6302 - 830.7950)

The study is **Acceptable**. The following issues were raised in the primary review. Storage stability was stated as "Accelerated data = 1.5 years storage. In process long term storage". It was not clear what this meant. Also, corrosion characteristics were unclear, where the registrant

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stated "Non-corrosive; corrosive that of water".

Note to RAL: It appears that the registrant is conducting storage stability studies, and that the product obviously will be as 'corrosive' as water might be to susceptible containers (i.e., iron). This reviewer feels that the product can appropriately be determined as non-corrosive, and that the registrant is conducting storage stability studies.

MRID 454769-04: Primary eye irritation - rabbit (870.2400)

The study is **Acceptable**. The end-use product was practically non-irritating to the eye, with slight discharge only being observed in one eye of one of the three male rabbits tested at 1 hour post-dosing. This places the test material in **Toxicity Category IV**.

MRID 454769-03. Request for waiver of any additional required acute toxicity testing for RootGro.

The registrant requests that the results of the acute toxicity studies for technical IBA be bridged to support the registration of RootGro. Acute exposure study results for technical IBA gave **Toxicity Category IV** for the oral route, **Toxicity Category IV** for the dermal route, and **Toxicity Category IV** for the pulmonary route. Technical IBA also was not irritating to the skin, and was not a dermal sensitizer. The rationale for the request was that IBA comprises 0.8% of the product, the surfactant comprises [REDACTED] the dye comprises [REDACTED] and the [REDACTED] comprises [REDACTED]. The primary reviewer supported the request "...provided there are no inerts of concern in the formulation."

Note to RAL: The registrant only provided an MSD Sheet for [REDACTED]. This inert is not of concern because the pH of the formulated product is 7.2-7.5. The dye is not of concern because of the low concentration in the product [REDACTED] and it is a List 3 inert which has been cleared for food use at 180.1001 (c) and (e). Likewise, there is no concern for the surfactant [REDACTED] a List 4B inert, which also has been cleared for food use at 180.1001 (c) and (e). Therefore, the request to bridge the acute toxicity data for the technical IBA for registration of the end-use product is supportable.

Manufacturing process information may be entitled to confidential treatment
Inert ingredient information may be entitled to confidential treatment

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Chemical: Indole-3-butyric acid

PC Code:
046701

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